REMARKS

Claim Rejections

Claims 1-7 and 11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of co-pending patent application No. 10/833,097.

Claim Objections

Claims 1 and 11 are objected to because of a spelling informality. Claims 12-14 are objected to because they depend from rejected claims.

Claim Amendments

In the current rejection of claims 1-7 and 11, the Examiner states that it is unclear how one achieves the detection of microorganism DNA because there is no recitation of attachment of the avidin or streptavidin complexes to anything. Furthermore, it is stated that the probes do not have any kind of label attached to them, according to claims 1-7 and 11.

To overcome Examiner's rejection of claim 1, an additional step as recited in the specification is added as new step (a). The method of claim 1 now comprises "amplifying the microorganism cDNA with bioactive primers." All subsequent steps are maintained and relettered to (b)-(i) as appropriate. This amendment to claim 1 clarifies how detection is achieved, for the reasons that follow.

The original specification at *e.g.* paragraphs [0035]-[0036] and [0049]-[0050] describes some embodiments of the invention as follows:

(i) In the construction of a bioactive primer, a detectable group such as biotin is first linked to a primer.

(ii) The bioactive primer is linked to cDNA after amplification of microorganism cDNA.

(iii) Bioactive primer–containing cDNA is hybridized with a probe.

(iv) Bioactive primer on probe-selected cDNA is conjugated with avidin or streptavidin.

(v) Avidin or streptavidin is linked to an enzyme.

(vi) Enzyme is reacted with substrate.

Point (iv) above comprises the "bridging step to instigate attachment of the avidin or streptavidin complexes" (May 25, 2006 Office Action at page 3, section 8, third paragraph). This bridging step is now made clear by reciting amplification by bioactive primers in claim 1, new step (a).

New step (a) in claim 1 is not new matter. Support from the specification for step (a) appears for example in prenumbered paragraphs [0034] and [0035]. According to Applicant's original specification at page 8, paragraph [0035], lines 12-13, "the bioactive primers are made by reacting DNA labeling reagent with the primers." Lines 20-21 from the same paragraph recite that the DNA labeling reagent comprises a detectable group that can be selected from the group consisting of biotin, fluorescence, acridinium ester and acridinium-9-carboxamide.

It is respectfully submitted that adding the step "amplifying the microorganism cDNA with bioactive primers" makes is clear how detection is ultimately achieved. The detectable group, such as biotin, is used in a DNA-labeling reagent which may react with the primers to form "bioactive primers" (defined in paragraph [0035]). Paragraph [0027] specifically teaches that biotinylated primer pairs can be used in PCR amplification for the present invention.

Additional support for new step (a) can be found in the specification preceding the Examples, at prenumbered paragraph [0049]. These paragraphs disclose and teach target amplification carried out prior to hybridization (which is step (b) of claim 1). The heading for paragraph [0049] is "Target amplification," and the written description discloses a PCR technique. In "Step II," the "PCR product from step I" (line 5 on page 13, paragraph [0049]) is added to a reaction mixture comprising bioactive primers for amplification. Reference can be made back to construction of bioactive primers as taught in paragraph [0035], and to paragraph [0027] which states that "PCR...must be used in conjunction with a detection technique to determine the results of amplification." Paragraph [0050] then teaches hybridization, which relates to step (b) of claim 1.

In view of the amendment to claim 1, adding new step (a) prior to steps (b)-(i), it is submitted that claim 1 now particularly points out and distinctly claims the subject matter which Applicant regards as the invention of claim 1. Step (a) is fully supported and taught in the original specification and is therefore not new matter. Furthermore, one of ordinary skill in the art, reading Applicant's original

specification, would be expected to understand the subject matter of claim 1 in such a way as to be able to make and use the invention of claim 1. Therefore, claim 1 now complies with 35 U.S.C. §112.

Claim 11, as currently written, already recites "bioactive primers" in element (b) of the system. It is therefore respectfully put forward that nothing more is necessary in claim 11 to clarify "how one achieves the detection" or how "avidin or streptavidin complexes to anything" (May 25, 2006 Office Action at page 3, section 8, third paragraph). Namely, the original specification at paragraph [0035]—description of "bioactive primers" of the invention, as discussed above in regards to claim 1—provides full 35 U.S.C. §112 support for the system of claim 11. One of ordinary skill in the art, reading Applicant's original specification, would be expected to understand the subject matter which Applicant regards as the invention in claim 11. Furthermore, this same artisan would understand how to make and use the invention of claim 11.

Claim 1 is amended to overcome the objection arising due to the misspelling of the term "avidin" in element (d). Claim 11, element (c) is similarly amended to spell avidin correctly. By these amendments, appropriate correction has been made.

Claim 1 is amended to recite "a method of detecting microorganism cDNA" rather than "a method of detecting microorganism DNA," to ensure proper antecedent basis for cDNA in element (a) of claim 1 and in claim 3. This amendment is not in response to an Examiner objection but is respectfully submitted to ensure full compliance with 35 U.S.C. §112. This amendment does not add new matter.

Claim 11 is amended to fix a grammatical informality (consecutive verbs describing the system). "A system for performing detection of microorganism cDNA..." now replaces "A system for performing detecting microorganism cDNA...." This amendment is not in response to an Examiner objection but is respectfully submitted to ensure full compliance with 35 U.S.C. §112. This amendment does not add new matter.

Claims 4-7 are amended to recite the correct relettered steps of amended claim 1. This amendment does not add new matter.

Double Patenting

To overcome the provisional rejection of claim 2 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of co-pending patent App. No. 10/833,097, following issuance of a patent for one of the

present invention and co-pending App. No. 10/833,097, Applicants hereby agree to file a terminal disclaimer for the remaining patent application. Such terminal disclaimer will be limited in scope to claim 2 of App. No. 10/729,980 and claim 3 of App. No. 10/833,097. Applicants believe that the present amendments to the claims address all of the issues raised in the May 25, 2006 Office Action, and thus place this application in condition for allowance. Accordingly, Applicants submit that their response to the Terminal Disclaimer requirement should be satisfactory, as there should be no reason for allowed claims to be terminally disclaimed over pending claims in another application. Therefore, upon agreement that the claims of the present application are in condition for allowance, Applicants request that the Examiner withdraw the requirement in this application in lieu of the current requirement in the co-pending application.

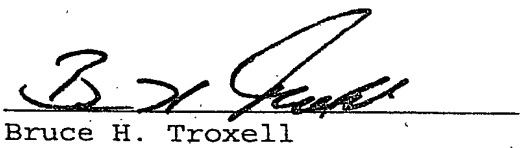
Summary

By this Amendment, Applicants have amended claims 1, 4-7, and 11 of this application. It is believed that the amended claims specifically set forth each element of Applicants' invention in full compliance with 35 U.S.C. §112. The claimed subject matter is described in sufficient detail to enable one having ordinary skill in the art to make and use Applicants' invention without undue experimentation. Claims 1 and 11, as well as dependent claims 2-7 and 12-14, should be allowed.

In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance, and such action is respectfully requested. Should any points remain in issue, which the Examiner feels could best be resolved by either a personal or telephonic interview, it is urged that the undersigned be contacted for such an interview.

Respectfully submitted,

Date: October 23, 2006

By: 

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